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#### Remarks

Claims 8-11 are pending in the present application. The Examiner has rejected pending Claims 8-11 as being non-enabling under 35 USC 112, first paragraph. The Examiner has also rejected pending Claims 8-11 as being indefinite under 35 USC 112, second paragraph.

Claims 8-10 are amended to further clarify these claims. No new matter has been added by this amendment.

The Examiner's rejection of the pending Claims shall now be addressed in the order made by the Examiner.

# Rejection of Claims 8-11 Under 35 USC 112, First Paragraph

Claims 8-11 are rejected under 35 USC §112, first paragraph, as not enabling one skilled in the art to make the invention. The Examiner states that the Specification fails to enable one of skill in the art to make the invention commensurate with the scope of the claims as it lacks direction or guidance for placing all of the products in the possession of the public without inviting more than routine experimentation.

Specifically, the Examiner states that, though the Specification does enable a phenyl R<sup>2</sup> group that has 1 or 2 nitro or amino groups at the meta position, the Specification does not provide enablement for a phenyl R<sup>2</sup> group that is substituted 3 or more times with nitro or amino groups. Further, the Examiner states that "No compound has ever been synthesized where a phenyl ring can support electron-withdrawing groups, such as nitro, in the ortho position."

Contrary to the Examiner's statement, the Specification does enable one of skill in the art to make

and use the invention of Claims 8-11.

The purpose of the enablement provision is to assure that the inventor provides sufficient information about the claimed invention so that a person of skill in the art can make and use it without undue experimentation relying on the Specification and the knowledge in the art. (See Scripps Clinic & Research Foundation v. Genentech, Inc., 18 USPQ2d 1896 (Fed. Cir. 1991).)

Contrary to the Examiner's statement, processes are know in the art for producing phenyl compounds that (1) are substituted at the ortho position with a nitro or amino group, and (2) are substituted 3 or more times with nitro and amino groups. Numerous examples of such compounds are present in the American Chemical Society registry of compounds. In demonstration of this fact, 19 different structures, from the ACS Registry, are attached which show compounds containing phenyl groups that are substituted at the ortho position with a nitro or amine group and compounds containing phenyl groups that are substituted 3 or more times with nitro or amine groups. Thus, utilizing the known methods in the art for making these compounds, one of skill in the art would be able, without undue experimentation, to make compounds of Claims 8-11 wherein the  ${\ensuremath{R^2}}$  group is a phenyl that is substituted at the ortho position and/or 3 or more times with nitro or amino groups

Thus, pending Claims 8-11 are improperly rejected as being non-enabling.

# Rejection of Claims 8-11 Under 35 USC 112, Second Paragraph

Claims 8-11 are rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicants claim as the invention.

### Claim 8

The Examiner states that, in Claim 8, the phrase "one or more  $C_1\text{--}C_6$  alkyl,  $C_1\text{--}C_6$  alkoxy, halo, nitro, amino or trifluoromethyl" is indefinite as there is no upper bound on the phrase "one or more".

Contrary to the Examiner's statement, the phrase "one or more" is not indefinite.

It is not required that an application describe claim limitations in detail greater than the invention warrants. (See Martin v. Mayer, 3 USPQ2d 1333 (Fed. Cir. 1987).) Rather, the application only needs description sufficient that it conveys to those skilled in the art that the applicant has invented the subject matter claimed. (See In re Kaslow, 217 USPQ 1089, 1096 (Fed. Cir. 1983).)

In Claim 8, the phrase "one or more  $C_1$ - $C_6$  alkyl,  $C_1$ - $C_6$  alkoxy, halo, nitro, amino or trifluoromethyl" relates to possible substitution of the group  $R^2$  wherein  $R^2$  can be a  $C_1$ - $C_6$  alkyl, trifluoromethyl or phenyl. It is well within the knowledge of one skilled in the art how many times a methyl, ethyl, propyl, butyl, pentyl, hexyl, trifluoromethyl or phenyl group may be substituted with one of the above-identified substituents. Therefore, based upon the disclosure provided in the present Application, does sufficiently describe to a skilled artisan the scope of the presently claimed invention.

Further, phrases such as "one or more" or "at least one", as used in chemical claims, are clearly understood by the skilled artisan. The clear understanding and acceptance of such claim language, by the skilled artisan, is further demonstrated by US Patent No. 5,684,135 (Claim

1), US Patent No. 5,653,960 (Claim 1), and US Patent No. 5,532,242 (Claim 1).

The Examiner also states that a phenyl ring cannot support an electron-withdrawing group, such as nitro, in the ortho position.

As previously described herein, in the response to the Examiner's rejection under 35 USC §112, first paragraph, the Examiner's statement is incorrect.

Further, the phrase "R2 is R2" is grammatically incorrect.

Claim 8 is amended to correct this typographical error.

### Claim 9

The Examiner states that Claim 9 produces a compound of formula VII but that it depends from Claim 8 which produces a compound of formula VI. The Examiner also states that there is no antecedent basis for formula VII.

As demonstrated on page 5 of the Specification, the process of Claim 9 converts a compound of formula VI, which is produced by the method of Claim 8, to produce a compound of formula VII.

Claim 9 is amended to clarify the claimed process and to provide antecedent basis for formula VII.

#### Claim 10

The Examiner states that Claim 10 produces a compound of formula VIII but that it depends from Claim 8 which produces a compound of formula VI.

As demonstrated on page 5 of the Specification, the process of Claim 10 converts a compound of formula VI, which is produced by the method of Claim 8, to produce a

compound of formula VIII.

Claim 10 is amended to clarify the claimed process.

Thus, pending Claims 8-11, as amended, are not properly rejected as being indefinite.

# Conclusion

Based on the foregoing, Applicant respectfully submits that the Examiner's rejection of Claims 8-11, as amended, under 35 USC 112, first and second paragraphs, as amended, under 35 USC 112, second paragraph, are not proper. Therefore, Applicant respectfully requests that the rejections of Claims 8-11 under 35 USC 112, first and second paragraphs, be withdrawn. Applicant further requests that a notice of allowance be issued for pending Claims 8-11.

Respectfully Submitted:

Date: 30 January 2003

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#### ATTACHMENT TO AMENDMENT

Version with Markings to Show Changes Made

DO NOT ENTER THIS VERSION

#### CLAIMS

8(once amended). A process for the preparation of a compound of the formula

$$\begin{array}{c|c} O & H & F & CO_2R^3 \\ O & H & N & N & N \\ H & H & F & F \end{array}$$

wherein  $R^2$  is  $[R^2$  is]  $C_1-C^6$  alkyl, trifluoromethyl, or phenyl which may be substituted by one or more of  $C_1-C_6$  alkyl,  $C_1-C_6$  alkoxy, halo, nitro, amino or trifluoromethyl, and

 $\mbox{\ensuremath{R^3}}$  is  $\mbox{\ensuremath{C_{1}\text{-}C_{6}}}$  alkyl, which comprises reacting a compound of the formula

$$\begin{array}{c|c} F & CO_2R^3 \\ \hline CI & N & V \\ \hline F & \end{array}$$

with a compound of the formula

9(once amended). A process [according to claim 8, further] comprising hydrolysis of the compound of formula VI with methanesulfonic acid, water and an organic solvent to form <u>a</u> [the] monomethanesulfonic acid salt of a compound of the formula

10 (once amended). A process [according to claim 8, further] comprising hydrolysis of the compound of formula VI with methanesulfonic acid and R<sup>3</sup>OH wherein R<sup>3</sup> is [as defined in claim 5]  $\underline{C_1-C_6}$  alkyl to form  $\underline{a}$  [the] monomethanesulfonic acid salt of  $\underline{a}$  [the] compound of the formula

466685-30-3



$$\begin{array}{c|c} & \text{OMe} \\ & \text{NO2} & \text{O} \\ & \text{N} & \text{S} \\ & \text{SMe} \end{array}$$

Commercial Sources

# No References

68507-75-5

~1 R f rence
REGISTRY (Copyright 2003 ACS)

476634-00-1

# N References

476307-07-0

$$\begin{array}{c|c} & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & \\ & & & \\ & &$$

# N References

481053-41-2

# ~1 Reference

29 January 2003

SciFinder

Page: 2

473734-52-0

$$^{\mathrm{NH}_2}$$
  $^{\mathrm{O}}$   $^{\mathrm{Me}}$   $^{\mathrm{C-N-Me}}$ 

~1 R ference REGISTRY (Copyright 2003 ACS) 229342-59-0

### ~2 References

# 29 January 2003

# SciFinder

Page: 2

449747-91-5

$$^{\mathrm{NH}\,2}_{\mathrm{H}_2\mathrm{N}}$$
  $^{\mathrm{Me}}_{\mathrm{NO}\,2}$ 

# ~1 Reference

30226-35-8

# N R ferences

441787-12-8

# ~1 Reference

162247-02-1

$$O_2$$
  $O_2$   $O_2$   $O_3$   $O_4$   $O_4$   $O_5$   $O_5$   $O_6$   $O_7$   $O_8$   $O_8$ 

### ~1 Reference

360779-11-9

$$0 \longrightarrow N \longrightarrow NH_2$$

$$N \longrightarrow NH_2$$

$$N \longrightarrow 0$$

$$N \longrightarrow 0$$

$$N \longrightarrow 0$$

# ~1 Reference

103025-39-4

### ~2 R ferences

# 29 January 2003

# SciFinder

Page: 2

103025-38-3

# ~2 References

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# SciFinder

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101410-95-1

$$0 \\ \text{Me} \\ 0 \\ \text{NH}_2 \\ \text{NH}_2$$

# ~1 Reference

91-125-10-9

# ~4 References

84432-53-1

$$0 \longrightarrow N \longrightarrow 0$$

# ~9 References

360779-11-9

$$\begin{array}{c|c} O_2 N & & & \\ & NH_2 & & \\ & NH_2 & & \\ & N & & O \\ & & O \\ & & O \\ \end{array}$$

# ~1 Ref rence

18128-07-9

$$H_2N$$
 $NH_2$ 
 $NH_2$ 
 $NH_2$ 

• 4 HCl

# N References